IBUPROFEN- ibuprofen tablet WALGREENS

612R Walgreens 0363-9612 Ibuprofen 200mg Caplets

DRUG FACTS

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

temporarily relieves minor aches and pain due to:

- backache
- headache
- menstrual cramps
- minor pain of arthritis
- muscular aches
- the common cold
- toothache

temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergy reaction, especially in people allergic to aspirin.

Symptoms may include:

- asthma (wheezing)
- blisters
- facial swelling
- hives
- rash
- shock
- skin reddening

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have bad stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug

- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

When using this product

take with food or milk if stomach upset occurs

Stop use and ask a doctor if

you experience any of the following signs of stomach bleeding:

- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better

you have symptoms of heart problem or stroke:

- chest pain
- trouble breathing
- weakness in one part or side of the body
- slurred speech
- leg swelling

pain gets worse or lasts more than 10 days

fever gets worse or lasts more than 3 days

redness or swelling is present in the painful area

any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions

do not take more than directed

the smallest effective dose should be used

adults and children 12 years and over:

- take 1 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years:

ask a doctor

Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? call **1-877-290-4008**

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(**CAPSULE-SHAPED TABLETS) SEE NEW WARNINGS INFORMATION

Varnish/Print Omit Area

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■ temporarily relieves minor aches and pains due to:

• backache • headache • menstrual cramps
• minor pain of arthritis • muscular aches

toothache

Active ingredient (in each captet) Purpose

Drug Facts

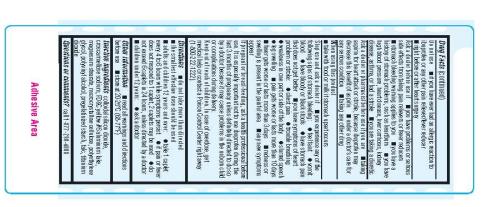
Drug Facts (continued)

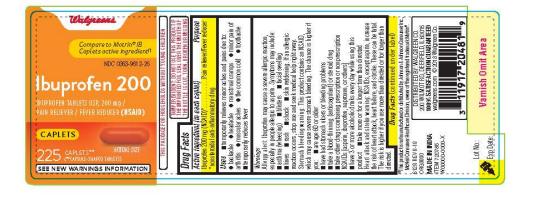
Varnish Omit

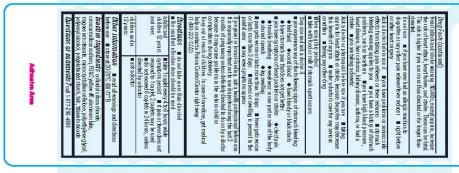
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Lot No.: Exp Date:

Varnish Omit









IBUPROFEN

ibuprofen tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-9612

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
STARCH, CORN (UNII: 08232NY3SJ)

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	120
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363- 9612-05	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
2	NDC:0363- 9612-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
3	NDC:0363- 9612-26	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
4	NDC:0363- 9612-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091237	12/11/2018	

Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(0363-9612)	

Revised: 11/2021 WALGREENS